D1 B1

a derivative or homologue thereof and a stabilizing agent, additives for maintaining pH and isotonicity and one or more pharmaceutically acceptable carriers wherein the pH of the composition is between about 3.5 and 6.5.

2. (Amended) A composition according to any one of claims 1 or 44 or 45 wherein the stabilizing agent facilitates reduced aggregation of LIF.

3. (Amended) A composition according to any one of claims 1 or 44 or 45 wherein the stabilizing agent facilitates a reduction in the deamidation of LIF.

D1 B2

6. (Amended) A composition according to claim 1 wherein the stabilizing agent is an agent which increases or maintains the conformational stability of LIF or its derivatives of homologues or functional equivalents thereof.

7. (Amended) A composition according to claim 6 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

D1 B3

14. (Amended) A composition comprising leukaemia inhibitory factor (LIF), additives for maintaining pH and isotonicity and one or more pharmaceutically acceptable carriers and/or diluents and wherein the composition has a pH of between about 3.5 and 6.5.

15. (Amended) A composition according to claim 14 wherein the aggregation of LIF is reduced over time.

16. (Amended) A composition according to claim 14 or 48 or 49 wherein the deamidation of LIF is reduced over time.

17. (Amended) A composition according to claim 14 or 48 or 49 where the pH is maintained by the presence of a buffer species selection from a phosphate, citrate and

B3 D1

acetate buffer.

21. (Amended) A method for preparing a composition comprising leukaemia inhibitory factor (LIF) or a derivative or homologue thereof and which exhibits reduced deamidation and/or aggregation of LIF or its derivative or homologues over time said method comprising admixing LIF or its derivative or homologue with a stabilizing agent and additives for maintaining pH and isotonicity.

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22. (Amended) A method according to claim 21 wherein the stabilizing agent is an agent which increases or maintains the conformational stability of LIF or its derivatives or homologues or a surfactant or functional equivalents thereof.

23. (Amended) A method according to claim 22 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a sugar and a pharmaceutically acceptable polymeric compound.

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28. (Amended) A method according to claim 21 wherein the additives for maintaining pH and isotonicty are selected from a phosphate, citrate and acetate buffer.

29. (Amended) A method according to claim 28 wherein the additives for maintaining pH and isotonicity are citrate or acetate buffer.

30. (Amended) A method according to claim 21 further comprising adjusting the pH to between about 3.5 and about 6.5.

B6 D1

32. (Amended) A method according to claim 21 further comprising admixing one or more pharmaceutically acceptable carriers and/or diluents.

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B7

34. (Amended) A method according to claim 54 wherein the stabilizing agent is selected from a polyhydric alcohol, a pharmaceutically acceptable salt, a buffer species, a

sugar and a pharmaceutically acceptable polymeric compound.

35. (Amended) A method according to claim 34 wherein the polyhydric alcohol is sorbitol.

36. (Amended) A method according to claim 34 wherein the surfactant is an anionic, cationic, amphoteric or non-ionic surfactant.

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37. (Amended) A method according to claim 36 wherein the surfactant is selected from a fatty alcohol, glyceryl ester and a fatty acid ester of a fatty alcohol or other alcohol.

B7

38. (Amended) A method according to claim 54 where the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative or a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

39. (Amended) A method according to claim 34 wherein the buffer species is selected from a phosphate, citrate and acetate buffer.

40. (Amended) A method according to claim 39 wherein the buffer species [isa] <u>is a</u> citrate or acetate buffer.

41. (Amended) A method according to claim 54 where the pH of the composition is between about 3.5 to about 6.5.

42. (Amended) A method according to claim 41 wherein the pH is between about 4.5 and about 5.5

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D1

43. (Amended) A composition according to claim 13 wherein LIF is present in an amount from about 0.1 μg/ml to about 100 mg/ml.

Please add the following new Claims 44-55:

44. (New) A composition according to claim 1 wherein the pH of the composition is between about 4.5 and 6.5.

45. (New) A composition according to claim 2 wherein the pH of the composition is between about 4.5 and 6.0.

D1

46. (New) A composition according to claim 6 wherein the stabilizing agent is a surfactant.

47. (New) A composition according to claim 9 wherein the stabilizing agent is polysorbate 20 and/or polysorbate 80.

B9

48. (New) A composition according to claim 14 wherein the composition has a pH of between about 4.5 and 6.5.

49. (New) A composition according to claim 48 wherein the composition has a pH of between about 4.5 and 6.0.

50. (New) A method according to claim 23 wherein the stabilizing agent is selected from a polysorbate, a polyoxyethylene derivative and a pharmaceutically acceptable polyoxyethylene-polyoxypropylene copolymer.

51. (New) A method according to claim 50 wherein the polysorbate is polysorbate 20 and/or polysorbate 80.

52. (New) A method according to claim 30 further comprising adjusting the pH to between about 4.5 and about 6.5.

53. (New) A method according to claim 30 further comprising adjusting the pH to between about 4.5 and 6.0.